Conclusions: Both gE/AS01$_B$ and gE/AS01$_E$ formulations and both schedules were immunogenic and well tolerated in autologous HCT recipients.

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Randomized, Double Blind, Placebo-Controlled Trial of a TNF Inhibitor (ETANERCEPT) for the Treatment of Idiopathic Pneumonia Syndrome (IPS) After Allogeneic Stem Cell Transplant (SCT). A Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Study

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IPS is a frequently fatal form of non-infectious pneumonia occurring early after allogeneic SCT. We conducted a phase III trial to investigate if a soluble TNF binding protein, etanercept (Enbrel® Amgen), when given with corticosteroids, improved management of IPS. The study was supported by the NHLBI and NCI, with etanercept supplied by Amgen. Eligible patients were ≥18 yrs, within 180 days post allo-SCT, with diffuse pulmonary infiltrates, and absence of active infection, sepsis syndrome, or cardiogenic shock. A negative BAL was required at study entry. Patients were randomized to receive etanercept (0.4 mg/kg/dose 2x/week x 4 weeks) or placebo, in addition to corticosteroids (2.0 mg/kg/day, with taper allowed after 7 days). Response was defined as survival with discontinuation of supplemental oxygen for >72 hours by day 28 of study. The trial was initially designed to enroll 120 patients, with sufficient power to identify a 25% response difference (30% to 55%) between study arms. Due to suboptimal accrual, inclusion criteria were modified and expected enrollment decreased to 60 patients, 30 per arm. The trial did not meet accrual goals and was stopped after enrolling 34 patients.
Results: Between 2007 and 2011, 34 patients (median age 46.6y, range 22-70 y) were randomized to receive etanercept (n=16) or placebo (n=18). Study arms were balanced for patient demographics, except for a higher incidence of AML in the placebo arm (50% vs 6%, $P = .02$). 50% of etanercept and 55% of placebo treated patients received all intended study doses, whereas 38% of etanercept and 6% of placebo treated patients received ≤25% of intended dosing (primarily investigator discretion). Response at day 28 and day 56, and overall survival were comparable between groups (Table 1). There were no differences in time to discontinuation of supplemental oxygen, incidence of grades 3-5 adverse events, infections, cumulative incidence of relapse, or grades 2-4 or 3-4 acute GVHD. Patients receiving ≤40% FiO2 at study entry had response rates of 91% (placebo) and 73% (etanercept) respectively. By comparison, responses in patients receiving >40% FiO2 at entry were 17% (1 of 6) on the placebo arm and 50% (2 of 4) on the etanercept arm.
Conclusion: No improvement in response or survival was noted when etanercept was added to corticosteroids for the treatment of IPS, though the small sample size significantly limits the statistical power of this study. Compared to historical reports, the response to corticosteroids alone was higher than anticipated supporting the importance of studying controls when evaluating a new therapy.

Table 1

	Etanercept arm	Placebo arm	*p*
Day 28 Response	62.5% (95%CI: 35.4-84.8)	66.7% (95%CI: 41.0-86.7)	.80
Day 56 Response	56.3% (95%CI: 29.9-80.3)	50.0% (95%CI: 26.0-74.0)	.72
6 month OS	50.0% (95%CI: 24.5-71.0)	33.3% (95%CI: 13.6-54.5)	
Median survival	171 days (95%CI: 11-362)	64 days (95%CI: 26-209)	
Log-rank (OS)			.51

TRANSPLANT DATA MANAGEMENT ORAL

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A Culture of Continuous Quality Improvement Improves Registry Data

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Background: To ensure the highest degree of accuracy of CIBMTR (Center for International Blood and Marrow Transplant Research) data, the University of Maryland Blood and Marrow Transplant team established a culture of continuous quality improvement. In early 2012, Minas and Ruehle reported the significance of auditing 10 commonly used data collection points. Since that time, their program set out to identify additional data points of significance.
Methods: The Blood and Marrow Transplant Program Manager and Data Managers continued to evaluate the quality of their data by selecting 19 additional data points for audit to assess the significance of adding these additional data points to the 10 commonly used ones. The CIBMTR forms of four subjects per month (40%) were randomly selected for audit from August 2011 to August 2012, for a total of 48 charts.
Results: Our results demonstrated that adding the extra data points covers 90% of the data reported while the commonly used data points cover only 50% of the data reported; thereby demonstrating a more comprehensive review of the information reported. Implementing the regular internal audit using the 10 commonly used data points demonstrated better percentage (range 89% to 100%) of data accuracy from that previously reported before implementing the regular internal audit. When the 19 additional data points were reviewed as a whole, there was a 96% accuracy rate. Corrective action was taken by reviewing all CIBMTR forms with less than 100% accuracy rate and correcting the data in the electronic database. Education is given on the individual level and for the group as trends become prevalent.
Conclusion: Implementing internal audits on a regular basis using the commonly used data points and the additional 19 data points have improved the accuracy of the data from what has been previously reported. By maintaining